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EXAMINER	
WHITEMAN, BRIAN A	
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1635	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/550,163	Applicant(s) SPLAWSKI ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9,25-30 and 69-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26,28,30 and 70* is/are allowed.

6)☒ Claim(s) *1,5-7,9,25,27,29,69 and 71-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). 13 & 14.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: .

DETAILED ACTION

Final Rejection

Claims 1, 5-7, 9, 25-30 and newly added claims 69-76 are pending examination.

Applicants' traversal, amendment of claims 1, 5, 7, 9, 25-30 and the specification, cancellation of claims 2-4, 8, 10-24, and 31-68, addition of claims 69-76 filed in paper no. 12 on 3/7/02 are acknowledged and considered.

Oath/Declaration

The objection to the oath/declaration remains because applicant, Mark Keating, has not yet provided a replacement.

It is noted that a replacement declaration and oath of inventor Mark Keating will be prepared and submitted to replace the defective oath. Page 7.

Drawings

A PTO 498 form was attached to office action, paper no. 10. A response with the corrected drawings or proposed corrections was not submitted with the response. Therefore, please supply in the response to this action corrected drawings. See 37 CFR 1.121(d) and 1.85(a). If corrected drawings are not submitted with the response, the response will be considered non-responsive.

Claim Objections

Applicants traverse that the objection to claims 1, 4-7, 25, 27, and 29 be withdrawn because of the amendment to claims, addition of claims, or cancellation of claims. See page 7.

Applicants' traversal is acknowledged and is found persuasive.

However, in view of the amended and new claims a new objection follows:

Claims 1, 7, 71, and 74 are objected to because of the following informalities: because of the misspelling of the word "complementary". Appropriate correction is required.

In addition, in claim 71, it is not apparent if the term "copies" is misspelled and was supposed to be the term "comprises". Clarification is requested.

Applicants' traversal is not found persuasive because it is not applicable to the new objections.

Applicants assert that the rejection of claims 2, 5, and 7-9 under 112 written description should be withdrawn because claims 5, 7, and 9 have been amended, claims 2 and 8 have been canceled; all primers encompass by claim 9 terminate at a base immediately adjacent to and 5' from a base selected from the group consisting of +22, +25, +161, and +170, which was disclosed on pages 72-73 as noted by the examiner. See page 7.

Applicants traversal is acknowledged and is found partially persuasive, the rejection for claims 2, 5, 7-8 are withdrawn. However, claim 9 remains rejected under 112 written description for the following reason.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9, as best understood, is readable on a genus of a polymorphic site which is used for performing a single base extension primer across a subsequence of SEQ ID NO: 2 or complement thereof is not claimed in a specific biochemical or molecular structure that could be

envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a species of isolated DNA encoding a polypeptide of SEQ ID NO: 2 comprising a mutation disclosed herein; an allelic variant of a DNA sequence in claim and/or allelic variant of amino acid sequence set forth in SEQ ID NO: 2, and a polymorphic site. The as-filed specification provides sufficient description of a species of an isolated DNA coding human MiRP1 in SEQ ID NO: 1. Furthermore, the as-filed specification further provides description of a species of SEQ ID NO: 1 comprising a Q9E, M54T, I57T, and T8A mutation in the sequence (pages 72-73). However, the as-filed specification does not provide sufficient description of a polymorphic site which can used for performing a single base extension reaction across a subsequence of SEQ ID NO: 2 or the complement thereof.

However, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of a polymorphic site in a subsequence of SEQ ID: 2; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of polymorphic sites that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient to support the present claimed invention directed to a genus a polymorphic site which can used in a single base extension reaction across a subsequence of SEQ ID NO: 2. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming unspecified polymorphic sites that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed polymorphic site that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicants assert that the rejection of claim 9 under 112 written description should be withdrawn because claim 9 has been amended; all primers encompass by claim 9 terminate at a

base immediately adjacent to and 5' from a base selected from the group consisting of +22, +25, +161, and +170, which was disclosed on pages 72-73 as noted by the examiner. See page 7.

Applicants' traversal is acknowledged and is not found persuasive because the claim still reads on any primer suitable for performing a single base extension reaction across a polymorphic site, which subsequence terminates at base immediately adjacent to and 5' from a base selected from several nucleotides listed above. The disclosure does not provide sufficient description of polymorphic sites other than the ones listed on pages 72-73 in SEQ ID NO: 1.

Claims 5-7 and 9 remain and new claims 72 and 73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) An isolated nucleic acid coding for a human MiRP1 polypeptide having the amino acid sequence set forth in SEQ ID NO: 2 or an isolated nucleic acid which is the complementary to said nucleic acid coding for a human MiRp1 polypeptide; 2) A primer suitable for performing a single base extension reaction across a polymorphic site set forth in SEQ ID NO: 1, which primer hybridizes to a subsequence of SEQ ID NO: 1 or the complement thereof, which subsequence terminates at base next to and 5' from a base selected from the group consisting of nucleotides numbers 95, 98, 234, or 243. The specification does not reasonably provide enablement for any other embodiment as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or

guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possession of a genus of polymorphic sites, which primer hybridizes to a subsequence of SEQ ID NO: 1 or the complement thereof, which subsequence terminates at base immediately adjacent to and 5' from a base selected from the group consisting of nucleotide numbers 95, 98, 234, or 243), particularly in view of the reasons set forth above, one skilled in the art would not have known how to use and make the claimed invention so that it would operate as intended.

With respect to claims encompassing using a nucleic acid probe which hybridizes specifically to the nucleotide sequence encoding SEQ ID NO: 2, the specification discloses and the claims recite probes that hybridize preferentially to the DNA (SEQ ID NO: 1) of human MiRP1 and four human MiRP1 nucleotide sequences mutated at a single amino acid, a) Q9E-hMiRP1, b) M54T-hMiRP1, c) I57T-hMiRP1, or d) T8A-hMiRP1 (page 73), but not to any other nucleic acid sequence. However, the state of the prior art as exemplified by Wallace et al. and Sambrook is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. Furthermore, the as-filed specification does not provide sufficient guidance to determine the structural and functional limitation of a nucleic acid probe which hybridizes specifically to the DNA of claims 5 and 72 under any stringent condition wherein said stringent hybridization condition prevents said nucleic acid probe from hybridizing to DNA encoding SEQ ID NO: 2 and/or any allelic

specific probe or primer which hybridizes to the DNA of claim 1 or an allelic variant thereof under any stringent condition. The lack of working examples in view of the prior art would result in an undue amount of experimentation for one skilled in the art to reasonably correlate probes composed of a 10mer fragment of nucleic acid sequence encoding SEQ ID NO: 2 to any other DNA probe that would meet the functional and structural limitations of the claimed embodiment. There are no suggestions as to what the target sites in the nucleic acid sequence encoding SEQ ID NO: 2 are or what modifications can be made while retaining the functional limitation. In addition, dependent claims 6 and 7 are the only claims to recite limitations on the nucleic acid (*e.g.* probe of claim 5 that 10-100 bases long; probe of claim 6 that **comprises** at least ten contiguous bases from a nucleic acid sequence encoding SEQ ID NO: 2 or the complement of thereof). Since the nucleotide sequence mentioned merely **comprises** at least ten contiguous nucleotides from a nucleotide sequence selected from SEQ ID NO: 2, it encompasses any random sequence of any length as long as it has a stretch of at least ten contiguous nucleotides that is the same as nucleic acid sequence encoding SEQ ID NO: 2. Furthermore, since there is no limitation that the claimed nucleic acid be complementary to the nucleotide sequence at the stretch of at least ten contiguous nucleotides that is the same as nucleic acid encoding SEQ ID NO: 2, the structural limitations encompass any nucleic acid consisting of 10 to 100 bases long. Thus, claim 6 encompasses any nucleic acid consisting of 10 to 100 in length and hybridizes to DNA of nucleic acid encoding SEQ ID NO: 2. Since the structural limitations of the claim clearly covers any nucleic acid that is 10 to 100 nucleotides in length and in view of the unpredictable nature of the art and lack of guidance with respect to appropriate modifications, one skilled in the art would have to make and test with further experimentation an

enormous number of nucleic acids that meet the structural limitations to determine which probes also meet the functional limitation. This amount of experimentation would result in undue experimentation for one skilled in the art. Therefore, based on the unpredictable nature of the invention and the state of the prior art, the limited guidance and working examples in the as-filed specification, and the extensive quantity of experimentation needed to identify the nucleic acids encompassed by the claims, it would require an undue amount of experimentation to identify or make the nucleic acids encompassed by the claims (*e.g.* a nucleic acid probe which hybridizes specifically to the DNA of claim 5 under stringent conditions wherein said stringent conditions are generic, see page 36, which cites preferred hybridization conditions) other than an isolated nucleic acid comprising of at least 10 nucleotides which hybridizes DNA encoding SEQ ID NO: 2. Furthermore, with respect to the claimed embodiment encompassing the use of any primer which hybridizes to the DNA encoding mutated polypeptide of SEQ ID NO: 2, it is not apparent to one skilled in the art in view of the concerns listed above encompassing probes how to make and/or use amino acid primers encoding any fragment of SEQ ID NO: 2. First, DNA is required for amplification of any DNA sequence. One skilled in the art would understand that several conditions for producing primers from oligonucleotides, typically 15-30 bases long, would need an undue amount of experimentation to determine what region of interest in the unknown amino acid sequence would not contain bases complementary to themselves or with each other. Thus, the disclosure is not enabled for any primer, which would amplify any isolated DNA sequence encoding SEQ ID NO: 2.

Also, the disclosure does not provide sufficient guidance for performing a single base extension (SBE) across a polymorphic site, since a polymorphic site is not described in such a

way that one skilled in the art would be able to perform the SBE without undue experimentation. The state of art defines a polymorphism "as a locus in which two or more alleles have gene frequencies greater than 0.01 (1%) in a population (Jorde et al., Medical Genetics, 2nd ed., Mosby, 1999, page 328)." "When this criterion is not fulfilled the locus is monomorphic (Jorde et al., page 328)." The applicants display four mutations in the human MiRP1 gene associated with arrhythmia (pages 72-73). Therefore, the specification provides sufficient guidance for performing a single base reaction across of a polymorphic site of SEQ ID NO: 1 selected from the four nucleotides numbered, listed on pages 72-73 of the disclosure. However, in view of the definition of a polymorphism, the mutations do not reasonably correlate to a polymorphism and/or any other polymorphic site in the human MiRP1 gene.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enabled for 1-2, listed above. One would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the application's disclosure. Furthermore, the disclosure does not provide sufficient guidance in view of Chiu et al., *Folding and Design*, 1998, pp. 23-228 and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016 (Fed. Cir. 1991) for making and/or using probes that hybridize to unknown DNA sequences encoding a mutated polypeptide of SEQ ID NO: 2.

Applicants traverse that the rejection for claims 1-9 and 24-30 under 112 enablement be withdrawn because: Claims 1-9 have been amended to canceled where appropriate to recite the nucleic acid sequences that were disclosed in the specification; With respect to claim 5, the examiner's opinion that any nucleic acid which hybridizes under stringent conditions to a nucleic

acid encoding MiRP1 will not necessarily have the same biological activity as wild-type MiRP1 it irrelevant since the claim is to a nucleic acid, not the protein, and the nucleic acid can be used a as a probe; With respect to claim 9 the specification notes the precise location of the polymorphic sites found in SEQ ID NO: 1 and it is these sites that are encompassed by the claims; Claims 24 has been canceled and claims 25-30 have been amended to recite cells transfected in vitro or vectors comprising the isolated nucleic acids as disclosed in the specification. See page 8.

Applicants' traversal is acknowledged and is found partially persuasive for the following reasons: the claimed invention is enabled for 1 and 2 listed above. However, the claimed invention is not enabled for an allele specific probe or primer which hybridizes to a nucleic acid encoding a polypeptide of SEQ ID NO: 2 under generic hybridization conditions for the reasons set forth above in the 112 enablement rejection. More specifically, the state of the art exemplified by Wallace and Sambrook teach that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. A sequence search of a nucleic acid sequence encoding SEQ ID NO: 2 suggest that there are probes that would meet the structural limitation of the claimed invention but not the functional limitation. For example, a probe 9 bases long used for a human MiRP1 gene encoding the polypeptide in SEQ ID NO: 2 could also be used as a probe or primer for hybridizing to a part of the hemochromatosis (HH) gene that is shown to be linked to the MHC on chromosome 6p21 (Feder, US Patent No. 5,872,237, abstract and SEQ ID NO: 20) or Murai et al. (Biochem. Biophys. Res. Commun., Vol. 161, abstract (M26685), 1989) teaches a 13 base pair sequence that is complementary to nucleotides 98-111 of applicants claims sequence comprising a nucleic

acid sequence encoding SEQ ID NO: 2. One skilled in the art would reasonably determine that the conditions set forth in specification are not considered highly stringent conditions (See McClean, http://www.ndsu.nodak.edu/instruct/mcclean/plsc731/dna/dna6.htm, pages 3-5, 1998), and in view of these conditions, it is not apparent to one skilled how to reasonably determine a probe or primer specific for a nucleic acid encoding MiRP1 polypeptide set forth in SEQ ID NO: 2 because other sequences having a lower degree of homology will bind to the probe requiring an undue amount of experimentation to reasonably determine how to specifically target the claimed sequence. Therefore, based on the limited guidance provided by the specification (e.g. generic hybridization conditions on page 36) and the lack of working examples in the specification, and the extensive quantity of experimentation needed to identify the probes or primers encompassed by the claims, it would be reasonable to conclude that it would require an undue amount of experimentation to identify the nucleic acids encompassed by the claims.

Applicants traverse that the rejection for claims 1-5 and 7-9 under 112 second be withdrawn because: Claims 2-4 have been canceled, Claims 1 and 5 have been amended to recite the specific hybridization conditions disclosed in the application; Claims 7 has been amended to refer to a nucleic acid encoding SEQ ID NO: 2, Claim 8 has been canceled and claim 9 has been amended to refer to SEQ ID NO: 1. See page 8.

Applicants' traversal is acknowledged and is found persuasive.

However, in view of the amended claims, a new ground of rejections follows:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 25 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "An in vitro cell transfected in vivo" in claim 25 is a relative term, which renders the claim indefinite. The phrase "An in vitro cell transfected in vivo" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the phrase.

The term "copies" in claim 71 is a relative term, which renders the claim indefinite. The term "copies" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term. The disclosure does not distinctly point out how a mutated sequence copies nucleotides 74-442 of SEQ ID NO: 1.

The applicants' traversal is not found persuasive because the traversal is not applicable to the new ground of rejections. It is noted that during a telephone conversation with applicants' representative, Dr. Michael Moran, the term "in vivo" should not be in claim 25 (See paper no. 13).

Claim Rejections - 35 USC § 102

To the extent that that claims read on a sequence complementary to a nucleic acid sequence coding for human MiRP1 polypeptide, the following 102 rejections apply.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 7, and 25 remain and new claims 69 and 71-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurtz et al (US Patent Nos. 5,620,892, 15 April 1997). Kurtz discloses a nucleotide sequence for human minK with 85 percent similarity that would hybridize to applicants' nucleotide sequence encoding the amino acid set forth in SEQ ID NO: 2 (column 2, lines 55-61, SEQ ID NO: 5). In addition, Kurtz teaches that oligonucleotides were used to produce portions of the TRK2 coding region (Fig.4, SEQ ID NO: 5) corresponding to the 5' (600bp) and 3' (800bp) ends of the coding region by polymerase chain reaction amplification of yeast genomic DNA (column 5, lines 10-14). Furthermore, Kurtz claims a modified cell, wherein the minK protein has the amino acid sequence encoded by a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 5 (column 39, lines 36-38).

Applicants assert that the rejection anticipated by Kurtz under 102(b) be withdrawn because examiner did not include any data showing a comparison of the sequences; Attorneys conducted a BLAST search of Kurtz's nucleic acid sequence vs. SEQ ID NO: 1 and Kurtz' protein vs. SEQ ID NO: 2, shows 45% identity and 74% similarity across the region of amino acid residues of SEQ ID NO: 2 (See page 9).

Applicants' traversal is acknowledged and is not found persuasive because the claim is a nucleic acid sequence encoding the amino acid sequence set forth in SEQ ID NO: 2 and the

examiner performed a search for a nucleic acid sequence encoding SEQ ID NO: 2 (a copy of the sequence search is enclosed with the office action) not a DNA vs. DNA or a protein vs. protein search. Kurtz teaches a nucleotide sequence with 84% identity claim 1. Kurtz further teaches a nucleotide sequence with 10+ contiguous bases of nucleic acid encoding a polypeptide of SEQ ID NO: 2 that is complementary to applicants' claimed nucleic acid sequence. More specifically, the stringent hybridization conditions set forth in the claimed invention still read on the prior art because the conditions allow for any sequence to hybridize with a nucleic acid encoding a polypeptide set forth in SEQ ID NO: 2. Furthermore, because of the phrase "complementary to said nucleic acid encoding for a human MiRp1 polypeptide", any sequence with one base pair that is complementary to a base pair from the sequence will read on the invention.

Suggest amending claim 1 to read as follows: An isolated nucleic acid coding for MiRP1 polypeptide having the amino acid sequence set forth in SEQ ID NO: 2 or an isolated nucleic acid which is the full complement of the nucleic acid coding for a human MiRP1 polypeptide.

Claims 1, 5, 6, 7, 25, 27, 29 remain and new claims 69 and 71-76 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg (NCI-CGAP, http://www.ncbi.nlm.nih.gov/ncicgap, AI339609). Strausberg teaches a MINK Human slow voltage-gated potassium channel cDNA sequence with 99.1 percent similarity to the applicants' nucleic sequence encoding the amino acid sequence set forth in SEQ ID NO: 2. Furthermore, Strausberg transfected a vector consisting of the sequence into cells to produce the cDNA. In addition, the nucleic acid encoding the applicant's amino acid sequence set forth in SEQ ID NO: 2 would hybridize to the cDNA sequence set forth by Strausberg. As evidence to the contrary,

the cDNA sequence taught by Strausberg displays all properties encompass in the claimed invention.

Applicants assert that the rejection anticipated by Strausberg under 102(a) be withdrawn because examiner the examiner asserts that the sequence is 99.1% similar to nucleic acid encoding SEQ ID NO: 2. This conclusion is wrong because the sequence corresponds to bases 11-499 of SEQ ID NO: 1 and lack sequence encoding amino acid residues 1-13 of SEQ ID NO: 2; Applicants have plan to submit under separate cover and at a date subsequent to this amendment a Declaration under 37 CFR 1.131 establishing a date prior to November 1998 (See pages 9 and 10).

Applicants' traversal is acknowledged and is not found persuasive because applicants have not provided a declaration under 37 CFR 1.131 to provide evidence for establishing a date of invention prior to November 1998. Furthermore, the sequence is 98% identical to SEQ ID NO: 1 and the conditions for hybridization set forth in the claim would allow the sequence taught by Strausberg to hybridize to a nucleic acid encoding applicants' SEQ ID NO: 2. In addition, applicants assert that the sequence taught by Strausberg corresponds to 11-499 of SEQ ID NO: 1 (See page 9 of applicants' response).

Claims 1, 5, 6, 7, 25, 27, 29 remain and claims 69 and 71-76 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg (NCI-CGAP, http://www.ncbi.nlm.nih.gov/ncicgap, AI246239). Strausberg teaches a MINK Human slow voltage-gated potassium channel cDNA sequence with 100 percent similarity to the applicants' nucleic sequence encoding the amino acid sequence set forth in SEQ ID NO: 2 and vectors

encoding the cDNA, and in vitro cells comprising the cDNA. Furthermore, Strausberg transfected a vector consisting of the sequence into cells to produce the cDNA. In addition, the nucleic acid encoding the applicant's amino acid sequence set forth in SEQ ID NO: 2 would hybridize to the cDNA sequence set forth by Strausberg. As evidence to the contrary, the cDNA sequence taught by Strausberg displays all properties encompass in the claimed invention.

Applicants assert that the rejection anticipated by Strausberg under 102(a) be withdrawn because examiner the examiner asserts that the sequence is 100% similar to nucleic acid encoding SEQ ID NO: 2. This conclusion is wrong because the sequence corresponds only to bases 118-489 of SEQ ID NO: 1 and the start codon of SEQ ID NO: 1 begins at base 74; Applicants have plan to submit under separate cover and at a date subsequent to this amendment a Declaration under 37 CFR 1.131 establishing a date prior to November 1998 (See pages 9 and 10).

Applicants' traversal is acknowledged and is not found persuasive because applicants have not provided a declaration under 37 CFR 1.131 to provide evidence for establishing a date of invention prior to November 1998. Furthermore, the sequence is 98% identical to SEQ ID NO: 1 and the conditions for hybridization would allow the sequence taught by Strausberg to hybridize to SEQ ID NO: 1. Furthermore, because of the phrase "complementary to said nucleic acid encoding for a human MiRp1 polypeptide", any sequence with one base pair that is complementary to a base pair from the sequence will read on the invention.

Suggest amending the claim to read as follows: An isolated nucleic acid coding for MiRP1 polypeptide having the amino acid sequence set forth in SEQ ID NO: 2 or an isolated

nucleic acid **which is the full complement** of the nucleic acid coding for a human MiRP1 polypeptide.

Claims 26, 28, 30, and 70 are in condition for allowance because they are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

DAVE T. NGUYEN
PRIMARY EXAMINER

Brian Whiteman
Patent Examiner, Group 1635
5/20/02